To:

#### From the INTERNATIONAL BUREAU

#### **PCT**

#### **NOTIFICATION OF ELECTION**

(PCT Rule 61.2)

United States Patent and Trademark Office

(Box PCT) Crystal Plaza 2 Washington, DC 20231 ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

| Date of mailing (day/month/y | year)     |
|------------------------------|-----------|
| 04 February 1999 (0          | 04.02.99) |

International application No.

PCT/GB98/01624

International filing date (day/month/year)
03 June 1998 (03.06.98)

Applicant's or agent's file reference

REP05729WO

Priority date (day/month/year) 04 June 1997 (04.06.97)

#### **Applicant**

WILLIAMS, Stephen, Charles et al

| 1. | The designated Office is hereby notified of its election made:  |
|----|---|
|    | X in the demand filed with the International Preliminary Examining Authority on:  |
|    | 21 December 1998 (21.12.98)   |
|    | in a notice effecting later election filed with the International Bureau on:  |
|    |   |
| 2. | The election X was  |
|    | was not   |
|    | made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b). |
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The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

C. Carrié

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35

#### PCT

#### NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

GILL JENNINGS & E Broadgate House 7 Eldon Street London EC2M 7LH **ROYAUME-UNI** 

From the INTERNATIONAL BUREAU

Date of mailing (day/month/year)

10 December 1998 (10.12.98)

Applicant's or agent's file reference

REP05729WO

IMPORTANT NOTICE

International application No. PCT/GB98/01624

International filing date (day/month/year)

Priority date (day/month/year)

03 June 1998 (03.06.98)

04 June 1997 (04.06.97)

**Applicant** 

**CAMBRIDGE SENSORS LIMITED et al** 

Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

CA, EP, JP, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

None

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 10 December 1998 (10.12.98) under No. WO 98/55856

#### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

#### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

J. Zahra

Facsimile No. (41-22) 740.14.35 Telephone No. (41-22) 338.83.38

| A. CLA | SSIFIC | ATION OF SUBJ | ECT MATTER  |
|--------|--------|---------------|-------------|
| IPC    | 6`     | GO1N27/40     | 3 G01N27/30 |

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 6 - 601N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

| C. DOCUMENTS CONSIDERED TO BE RELEVANT |   |                       |  |
|--|---|-----------------------|--|
| Category ·                             | Citation of document, with indication, where appropriate, of the relevant passages                              | Relevant to claim No. |  |
| Y                                      | EP 0 215 446 A (FUJI PHOTO FILM CO LTD) 25<br>March 1987<br>see page 6, line 8 - page 7, line 3;<br>figures 1,2 | 1,8                   |  |
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| Α                                      | EP 0 271 102 A (HORIBA LTD) 15 June 1988 see page 5, line 35 - page 6, line 15                                  | 1                     |  |

| Further documents are listed in the continuation of box C.  | Patent family members are listed in annex.   |
|---|--|
| <ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not</li> </ul>                                     | T" later document published after the international filing date<br>or priority date and not in conflict with the application but   |
| considered to be of particular relevance "E" earlier document but published on or after the international filing date   | cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention   |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention                     |
| "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filling date but                         | cannot be considered to involve an inventive step when the<br>document is combined with one or more other such docu-<br>ments, such combination being obvious to a person skilled<br>in the art. |
| later than the priority date claimed  Date of the actual completion of theinternational search  | "&" document member of the same patent family  Date of mailing of the international search report  |
| 26 August 1998  | 02/09/1998   |
| Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2   | Authorized officer   |
| NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016   | Duchatellier, M  |

## INTERNATIONAL SEARCH REPORT

| Category 3 | citation DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication where appropriate, of the relevant passages | Relevant to claim No.  |
|------------|---|------------------------|
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|            | see page 6, line 37 - line 56; figures 1,2  |                        |
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|            | July 1995   | , , ,                  |
|            | see column 2, line 21 - line 23   |                        |
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## INTERITIONAL SEARCH REPORT

Information on patent family members

| ational | Application No |
|---------|----------------|
|         | 98/01624       |

| Patent document cited in search repo | rt | Publication date | i              | Patent family<br>member(s) | Publication date |
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## INTERICTIONAL SEARCH REPORT

Information on patent family members

| utiona | Application No |  |
|--------|----------------|--|
| PCT/GB | 98/01624       |  |

| Ratent document cited in search report | Publication date | Patent family member(s)                      | Publication date                       |
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### PATENT COOPERATION TREATY

## **PCT**

| REC'D | 1 3 SEP 1999 | l |
|-------|--------------|---|
| WIP   | PCT          |   |

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference FOR FURTHER ACTION  |                                    |   | See N FOR FURTHER ACTION Prelir  | Notification of Transmittal of International minary Examination Report (Form PCT/IPEA/416)                 |
|---|------------------------------------|---|--|--|
| REP0572   | 9WC                                | )<br>                                       |  |  |
| International application No. International filing date (day/month/year) Priority date (day/month/year) |                                    |   |  |  |
| PCT/GB9   |                                    |   | 03/06/1998   | 04/06/1997   |
| Internationa<br>G01N27/   |                                    | nt Classification (IPC) or                  | national classification and IPC  |  |
| Applicant   |                                    |   |  |  |
| CAMBRII   | OGE                                | SENSORS LIMITED                             | ) et al.   |  |
| and is  | trans                              | smitted to the applican                     | mination report has been prepared by thi t according to Article 36.  of 5 sheets, including this cover sheet.                        | is International Preliminary Examining Authority   |
| ⊠ T<br>b<br>. (s  | his re<br>een a<br>see R           | port is also accompan                       | nied by ANNEXES, i.e. sheets of the desc<br>pasis for this report and/or sheets contain<br>607 of the Administrative Instructions un | cription, claims and/or drawings which have hing rectifications made before this Authority ander the PCT). |
| 3. This r   | _                                  | contains indications re                     | elating to the following items:  |  |
| П   |                                    |   |  |  |
| 111   |                                    |   | f opinion with regard to novelty, inventive  | step and industrial applicability  |
| IV  |                                    | Lack of unity of inver                      | ition  |  |
| ٧   | ×                                  | Reasoned statement<br>citations and explana | t under Article 35(2) with regard to noverty<br>ations suporting such statement  | y, inventive step or industrial applicability;   |
| VI  |                                    | Certain documents                           |  |  |
| VII   | $\boxtimes$                        | Certain defects in the                      | e international application  |  |
| VIII  |                                    | Certain observations                        | on the international application   |  |
|   |                                    |   | Date of comple   | etion of this report   |
| Date of sub   | omissi                             | on of the demand                            | ` ·  |  |
| Date of sub   |                                    | on of the demand                            |  | 0 8. 09. 99  |
| 21/12/19<br>Name and  | 98<br>mailin                       | g address of the internation                |  | 0 8. 09. 99  |
| 21/12/19<br>Name and  | 98<br>mailin                       | g address of the internation                |  | 0 8. 09. 99  |
| 21/12/19<br>Name and  | 98<br>mailin<br>exam<br>Eur<br>D-8 | g address of the internation                | onal Authorized office Komenda, F  | 0 8. 09. 99  |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB98/01624

| l. Bas | is of | the | rej | port |
|--------|-------|-----|-----|------|
|--------|-------|-----|-----|------|

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

|    | the | report since they a                   | o not contain amendments.).   |                               |                       |                         |
|----|-----|---------------------------------------|---|-------------------------------|-----------------------|-------------------------|
|    | Des | cription, pages:                      | •   |                               |                       |                         |
|    | 1-9 |                                       | as originally filed   |                               |                       |                         |
|    | Cla | ims, No.:                             |   |                               |                       |                         |
|    | 8   |                                       | as originally filed   |                               |                       |                         |
|    | 1-7 |                                       | as received on  | 14/05/1999                    | with letter of        | 12/05/1999              |
|    | Dra | wings, sheets:                        |   |                               |                       |                         |
|    | 1/1 |                                       | as originally filed   |                               |                       |                         |
| 2. | The | amendments have                       | e resulted in the cancellation of:                                    |                               |                       |                         |
|    |     | the description,                      | pages:  |                               |                       |                         |
|    |     | the claims,                           | Nos.:   |                               |                       |                         |
|    |     | the drawings,                         | sheets:   |                               |                       |                         |
| 3. |     | This report has be considered to go l | een established as if (some of) the beyond the disclosure as filed (F | ne amendmer<br>Rule 70.2(c)): | nts had not been made | e, since they have been |
| 4. | Add | litional observation                  | s, if necessary:  |                               |                       |                         |

### INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/GB98/01624

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes:

Claims 1-8

No:

Claims

Inventive step (IS)

Yes:

Claims 1-8

No:

Claims

Industrial applicability (IA)

Yes:

Claims 1-8

No:

Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

#### Section V:

Reference is made to the following document:

D1 = US-A-5 628 890

Document D1 reveals a device for use in the electrochemical analysis of an N: analyte in a liquid sample and comprises:

a non-conductive substrate (1, reference signs according to figure 1 of D1); a conductive layer (2), deposited on the substrate, in two parts (4, 5), defining a non-conducting gap therebetween;

an analyte-specific reagent (8) coated on the conductive layer, on one side of the gap:

a spacer layer (7) deposited over the conductive layer;

a monofilament mesh (9) coated with a surfactant (column 4, lines 56 to 61), the mesh being laid over the reagent, the reference electrode and the spacer layer; and

a second non-conductive layer (11) adhered to the mesh layer, but not coextensive therewith, thereby providing a sample application area (12).

The difference between the device of D1 and that of claim 1 is that according to the latter the application area is at one edge of the mesh (whereas in D1 the application area is "on top" of the device) (Article 33(2) PCT).

The above distinguishing feature is also present in claims 2 to 8 (Article 33(2) PCT).

IS: Starting from D1, the technical problem to be solved is to provide a device for use in the electrochemical analysis which device allows for sample collection without the need of aiming at the application area.

The solution for said problem is to locate the application area at one edge of the mesh i.e. of the device.

The other documents of the international search report do not disclose devices

where the application area is located at one edge. They all have the application area "on top" of the device onto which a sample solution is dropped. Since, moreover, the above solution is not obvious per se, an inventive activity is acknowledged for claims 1 to 8 (Article 3(3) PCT).

IA: Industrial applicability is also acknowledged (Article 33(4) PCT).

#### Section VII:

- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art 1) disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
- The independent claims are not in the two-part form in accordance with Rule 2) 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
  - If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claims are known from document D1 (see the PCT Guidelines PCT/GL/3 III, 2.3a).
- The features of the device claims are not provided with reference signs placed in 3) parentheses (Rule 6.2(b) PCT).

#### CLAIMS

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- 1. A device for use in the electrochemical analysis of an analyte in a liquid sample, which comprises:
  - a non-conducting substrate;
- a conductive layer, deposited on the substrate, in two parts, defining a non-conducting gap therebetween;
- an analyte-specific reagent coated on the conductive layer, on one side of the gap;
- a reference electrode on the conductive layer, on the other side of the gap;
  - a spacer layer deposited over the conductive layer;
  - a monofilament mesh coated with a surfactant or chaotropic agent, the mesh being laid over the reagent, the reference electrode and the spacer layer; and
- a second non-conductive layer, adhered to the mesh layer, but not coextensive therewith, thereby providing a sample application area on the mesh.
  - 2. A device according to claim 1, wherein the reagent is free of filler having both hydrophobic and hydrophilic surface regions.
  - 3. A device according to claim 1 or claim 2, wherein the analyte is glucose and the reagent is glucose dehydrogenase.
  - 4. A device according to any preceding claim, wherein the mesh is treated with a surfactant.
  - 5. A device according to any preceding claim, wherein the mesh is additionally coated with a cell lytic agent.
  - 6. A device according to any preceding claim, wherein the conductive layer comprises graphite particles, carbon particles and a polymer binder.
  - 7. A device according to claim 6, wherein the graphite particles have an average size of 1-20  $\mu m$  and a surface area of 1-50 m<sup>2</sup>/g, and the carbon particles have an average size of 5-70 nm and a surface area of less than 150 m<sup>2</sup>/g.

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Replaced by article 34



INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

**GILL JENNINGS & EVERY Broadgate House** 7 Eldon Street London EC2M 7LH **GRANDE BRETAGNE** 

## RECEIVED

10 SEP 1999

### PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY **EXAMINATION REPORT** 

(PCT Rule 71.1)

GILL JENNINGS & EVERY

03/06/1998

Date of mailing (day/month/year)

0 8, 09, 99

IMPORTANT NOTIFICATION

Applicant's or agent's file reference

**REP05729WO** 

International filing date (day/month/year)

Priority date (day/month/year)

04/06/1997

PCT/GB98/01624

International application No.

**Applicant** 

CAMBRIDGE SENSORS LIMITED et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

**European Patent Office** D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Authorized officer

Reddy-Lehocki, J

Tel.+49 89 2399-2288







## **PCT**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| • •                      |                 | nt's file reference  | FOR FURTHER ACTION   |                 | cation of Transmittal of Intern<br>y Examination Report (Form |                                       |
|--------------------------|-----------------|--|--|-----------------|---|---------------------------------------|
| REP0572                  |                 |  |  |                 | <del></del>   |                                       |
| International            | • •             |  | International filing date (day/mo  | nth/year)       | Priority date (day/month/)                                    | /ear)                                 |
| PCT/GB9                  |                 |  | 03/06/1998   |                 | 04/06/1997  |                                       |
| Internationa<br>G01N27/4 |                 | nt Classification (IPC) or na  | ational classification and IPC   |                 |   |                                       |
| Applicant                |                 |  |  |                 |   |                                       |
| CAMBRI                   | OGE             | SENSORS LIMITED  | et al.   |                 |   | · · · · · · · · · · · · · · · · · · · |
| 1. This in and is        | nterna<br>trans | ational preliminary exam<br>smitted to the applicant   | nination report has been prepa<br>according to Article 36.   | red by this Int | ternational Preliminary Ex                                    | camining Authority                    |
| 2. This F                | REPO            | RT consists of a total of  | f 5 sheets, including this cove  | r sheet.        | •   |                                       |
| be<br>(s                 | een a<br>see R  | mended and are the ba<br>ule 70.16 and Section 6   | od by ANNEXES, i.e. sheets of<br>sis for this report and/or sheet<br>607 of the Administrative Instru                            | s containing r  | rectifications made before                                    | gs which have a this Authority        |
| These                    | ann             | exes consist of a total of   | f 1 sheets.  |                 | •   |                                       |
|                          |                 |  |  |                 |   | •                                     |
| 3. This r                | eport           | Basis of the report Priority Non-establishment of the Lack of unity of invention Reasoned statement to | ating to the following items:  opinion with regard to novelty, ion under Article 35(2) with regard ions suporting such statement | to novelty, in  |   |                                       |
| VI                       |                 | Certain documents ci   |  |                 |   |                                       |
| VII                      | ×               | Certain defects in the   | international application  |                 |   |                                       |
| VIII                     |                 | Certain observations of  | on the international application   |                 |   |                                       |
| Date of sub              | omissi          | on of the demand   | Date   | of completion   | of this report  |                                       |
| 21/12/19                 | 98              |  |  |                 | 0 8. 09. 99   |                                       |
|                          | exam            | g address of the internation<br>ining authority:<br>opean Patent Office                                | al Aut   | orized officer  |   | ST TOPES MILES                        |
| 9))                      | D-8             | opean Patent Office<br>0298 Munich<br>. +49 89 2399 - 0 Tx: 5236                                       |  | menda, P        |   |                                       |
|                          |                 | : +49 89 2399 - 4465   |  | nhone No. +49   | 89 2399 2777  | Child Spine . Spine                   |



International application No. PCT/GB98/01624

#### I. Basis of the report

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

|    | uie  | epon since mey u     | o not comain amendments.j.  |            |                |                            |
|----|------|----------------------|---|------------|----------------|----------------------------|
|    | Des  | cription, pages:     |   |            |                |                            |
|    | 1-9  |                      | as originally filed   |            |                | ·                          |
|    | Clai | ms, No.:             |   |            |                |                            |
|    | 8    |                      | as originally filed   |            |                |                            |
|    | 1-7  |                      | as received on  | 14/05/1999 | with letter of | 12/05/1999                 |
|    | Dra  | wings, sheets:       |   |            |                |                            |
|    | 1/1  |                      | as originally filed   |            |                |                            |
| 2. | The  | amendments hav       | e resulted in the cancellation of:                                    |            |                |                            |
|    |      | the description,     | pages:  |            |                |                            |
|    |      | the claims,          | Nos.:   |            |                |                            |
|    |      | the drawings,        | sheets:   |            |                |                            |
| 3. |      |                      | een established as if (some of) t<br>beyond the disclosure as filed ( |            |                | made, since they have been |
| 4. | Add  | litional observatior | ns, if necessary:   |            |                |                            |

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB98/01624

- V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- 1. Statement

Novelty (N)

Yes:

Claims 1-8

No:

o: Claims

Inventive step (IS)

Yes:

Claims 1-8

No:

Claims

Industrial applicability (IA)

Yes:

Claims 1-8

No:

Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

## INTERNATIONAL PRELIMINARY InterEXAMINATION REPORT - SEPARATE SHEET

#### Section V:

Reference is made to the following document:

D1 = US-A-5 628 890

N: Document D1 reveals a device for use in the electrochemical analysis of an analyte in a liquid sample and comprises:

a non-conductive substrate (1, reference signs according to figure 1 of D1); a conductive layer (2), deposited on the substrate, in two parts (4, 5), defining a non-conducting gap therebetween;

an analyte-specific reagent (8) coated on the conductive layer, on one side of the gap:

a spacer layer (7) deposited over the conductive layer;

a monofilament mesh (9) coated with a surfactant (column 4, lines 56 to 61), the mesh being laid over the reagent, the reference electrode and the spacer layer; and

a second non-conductive layer (11) adhered to the mesh layer, but not coextensive therewith, thereby providing a sample application area (12).

The difference between the device of D1 and that of claim 1 is that according to the latter the application area is <u>at one edge</u> of the mesh (whereas in D1 the application area is "on top" of the device) (Article 33(2) PCT).

The above distinguishing feature is also present in claims 2 to 8 (Article 33(2) PCT).

IS: Starting from D1, the technical problem to be solved is to provide a device for use in the electrochemical analysis which device allows for sample collection without the need of aiming at the application area.

The solution for said problem is to locate the application area at one edge of the mesh i.e. of the device.

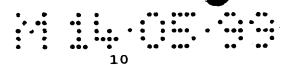
The other documents of the international search report do not disclose devices

where the application area is located at one edge. They all have the application area "on top" of the device onto which a sample solution is dropped. Since, moreover, the above solution is not obvious per se, an inventive activity is acknowledged for claims 1 to 8 (Article 3(3) PCT).

IA: Industrial applicability is also acknowledged (Article 33(4) PCT).

#### Section VII:

- 1) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.
- 2) The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
  - If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claims are known from document D1 (see the PCT Guidelines PCT/GL/3 III, 2.3a).
- 3) The features of the device claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).



#### CLAIMS

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1. A device for use in the electrochemical analysis of an analyte in a liquid sample, which comprises:

a non-conducting substrate;

a conductive layer, deposited on the substrate, in two parts, defining a non-conducting gap therebetween;

an analyte-specific reagent coated on the conductive layer, on one side of the gap;

a reference electrode on the conductive layer, on the other side of the gap;

a spacer layer deposited over the conductive layer;

a monofilament mesh coated with a surfactant or chaotropic agent, the mesh being laid over the reagent, the reference electrode and the spacer layer; and

a second non-conductive layer, adhered to the mesh layer, but not coextensive therewith, thereby providing a sample application area at one edge of the mesh.

- 2. A device according to claim 1, wherein the reagent is free of filler having both hydrophobic and hydrophilic surface regions.
- 3. A device according to claim 1 or claim 2, wherein the analyte is glucose and the reagent is glucose dehydrogenase.
- 4. A device according to any preceding claim, wherein the mesh is treated with a surfactant.
  - 5. A device according to any preceding claim, wherein the mesh is additionally coated with a cell lytic agent.
  - 6. A device according to any preceding claim, wherein the conductive layer comprises graphite particles, carbon particles and a polymer binder.
  - 7. A device according to claim 6, wherein the graphite particles have an average size of 1-20  $\mu m$  and a surface area of 1-50  $m^2/g$ , and the carbon particles have an average size of 5-70 nm and a surface area of less than 150  $m^2/g$ .

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|   | For re  | ceiving Office use only  |
|---|---|--|
| PCT   |   |  |
|   | International Application                                     | No.  |
| REQUEST   | International Filing Date                                     |  |
| The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.  | Name of receiving Office                                      | and "PCT International Application"  |
|   | Applicant's or agent's file (if desired) (12 characters ma    | DEDIS // YWO   |
| Box No. I TITLE OF INVENTION ELECTRODES FOR THE MEASUREMENT OF ANAL IN SMALL SAMPLE VOLUMES                                   | YTES  |  |
| Box No. II APPLICANT  |   |  |
| Name and address: (Family name followed by given name; for designation. The address must include postal                       |   | This person is also inventor.  |
| Cambridge Sensors Limited Downhams House  |   | Telephone No.  |
| Downhams Lane<br>Cambridge  |   | <u> </u>   |
| CB4 1XT   | •   | Facsimile No.  |
| United Kingdom  |   | Teleprinter No.  |
| State (i.e. country) of nationality:  | State (i.e. country) of                                       | residence:   |
|   |   | te United States  f America only  the States indicated in the Supplemental Box |
| Box No. III FURTHER APPLICANTS AND/OR (FUI  | RTHER) INVENTORS  |  |
| Name and address: (Family name followed by given name; for designation. The address must include postar                       |   | This person is:  |
| WILLIAMS, Stephen Charles P.O. 3559   |   | applicant only   |
| 500 Stone Pine Road<br>Half Moon Bay  |   | X applicant and inventor   |
| CA 94019<br>USA   |   | inventor only (if this check-box is marked, do not fill in below.)             |
| State (i.e. country) of nationality:  | State (i.e. country) of                                       | residence:<br>US   |
|   |   | the United States indicated in the States indicated in the Supplemental Box    |
| X Further applicants and/or (further) inventors are indicate  | d on a continuation sheet.                                    |  |
| Box No. IV AGENT OR COMMON REPRESENTAT  | IVE; OR ADDRESS FO  | OR CORRESPONDENCE  |
| The person identified below is hereby/has been appointed to a of the applicant(s) before the competent International Authorit |   | gent common representative   |
| Name and address: (Family name followed by given name; for designation. The address must include posta                        | a legal entity, full official<br>l code and name of country.) | Telephone No. +44 171 377 1377   |
| Gill Jennings & Every Broadgate House   |   | Facsimile No.  |
| 7 Eldon Street  |   | +44 171 377 1310   |
| London  |   | Teleprinter No.  |
| EC2M 7LH United Kingdom   |   | (051) 22765 GILPAT G   |
| Mark this check-box where no agent or common repr   |   | <u> </u>   |
| to indicate a special address to which correspondence   | should be sent.   |  |

| Continuation of Box No. III FURTHER APPLICANTS AND/O   | R (FURTHER) INVENTORS   |
|--|---|
| If none of the following sub-boxes is used, this sha   | eet is not to be included in the request.   |
| Name and address: (Family name followed by given name; for a legal enti-<br>designation. The address must include postal code and to | ty, full official name of country.) This person is:                                     |
| YON-HIN, Bernadette  | applicant only  |
| Cambridge Sensors Limited  | appnoant o,   |
| Downhams House   | X applicant and inventor  |
| Downhams Lane<br>Cambridge   |   |
| CB4 1XT  | inventor only (if this check-box is marked, do not fill in below.)                      |
| United Kingdom   | is marked, we not just in occurry   |
| State (i.e. country) of nationality:  GB   | (i.e. country) of residence: GB   |
| This person is applicant for the purposes of:  all designated all designated States of the United States of A                        | America X of America only the States indicated in the Supplemental Box                  |
| Name and address: (Family name followed by given name; for a legal ent designation. The address must include postal code and         | ity, full official name of country.)  This person is:                                   |
| BLAIR, Neil  | applicant only  |
| 122 Limes Road   |   |
| Hardwick<br>Cambridge  | X applicant and inventor  |
| CB3 7XU  |   |
| United Kingdom<br>GB   | inventor only (if this check-box is marked, do not fill in below.)                      |
| State (i.e. country) of nationality: State   | (i.e. country) of residence:  |
| GB   | GB-   |
| This person is applicant for the purposes of:  all designated states the United States of A  | except X the United States of America only the States indicated in the Supplemental Box |
| Name and address: (Family name followed by given name; for a legal ent designation. The address must include postal code and         | ity, full official name of country.) This person is:                                    |
|  | applicant only  |
|  | applicant and inventor  |
|  | inventor only (if this check-bax is marked, do not fill in below.)                      |
|  |   |
| State (i.e. country) of nationality:  State  | (i.e. country) of residence:  |
| This person is applicant for the purposes of:  all designated states the United States of  | except the United States the States indicated in America only the Supplemental Box      |
| Name and address: (Family name followed by given name; for a legal endesignation. The address must include postal code and           | tity, full official name of country.)  This person is:                                  |
|  | applicant only  |
|  | аррисан от  |
|  | applicant and inventor  |
|  | inventor only (if this check-box is marked, do not fill in below.)                      |
| State  | (i.e. country) of residence:  |
| State (i.e. country) of nationality:  State  | (i.e. country) of residence.  |
| This person is applicant for the purposes of:  all designated states the United States of  | except America the United States the States indicated in the Supplemental Box           |
| Further applicants and/or (further) inventors are indicated on anot  | her continuation sheet.   |

| Box No.V    | DESIGNATION OF STATES  |  |
|-------------|--|--|
| The followi | ng designations are hereby made under Rule 4.9(a) (  | mark the applicable check-boxes; at least one must be marked):   |
| Regional Pa | atent  |  |
| ☐ AP        | ARIPO Patent: GH Ghana, GM Gambia, KE Keny UG Uganda, ZW Zimbabwe, and any other State w   | a, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland,<br>which is a Contracting State of the Harare Protocol and of the PCT  |
| □ EA        | Eurasian Patent: AM Armenia, AZ Azerbaijan, BY   | Belarus, KG Kyrgyztan, KZ Kazakstan, MD Republic of Turkmenistan, and any other State which is a Contracting   |
| Х ЕР        | European Patent: AT Austria, BE Belgium, CH and ES Spain, FI Finland, FR France, GB United King  | d LI Switzerland and Liechtenstein, DE Germany, DK Denmark, edom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, weden, and any other State which is a Contracting State of the |
| □ 0A        | OAPI Patent: BF Burkina Faso, BJ Benin, CF Cent<br>CM Cameroon, GA Gabon, GN Guinea, ML Mali,<br>and any other State which is a member State of OA | ntral African Republic, CG Congo, CI Côte d'Ivoire, , MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, API and a Contracting State of the PCT (if other kind of protection |
| National Pa | tent (if other kind of protection or treatment is desired, spec  | cify on dotted line):  |
|             | Albania  | LT Lithuania   |
| ☐ AM        | Armenia  | LU Luxembourg  |
| ☐ AT        | Austria  | LV Latvia  |
| ☐ AU        | Australia  | MD Republic of Moldova   |
| ☐ AZ        | Azerbaijan   | MG Madagascar  |
| ☐ BA        | Bosnia & Herzogovina   | MK The former Yugoslav Republic of Macedonia   |
| □ вв        | Barbados   | ***************************************  |
| ☐ BG        | Bulgaria   | MN Mongolia  |
| ☐ BR        | Brazil   | MW Malawi  |
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| ☐ FI        | Finland  | SI Slovenia  |
| □ GB        | United Kingdom   | SK Slovakia  |
|             | Georgia  | SL Sierre Leone  |
| │ 🔲 СОН     | Ghana  | TJ Tajikistan  |
| _           | I Gambia   | TM Turkmenistan  |
|             | V Guinea-Bissau  | TR Turkey  |
| ∐ жо        | Hungary  | TT Trinidad and Tobago   |
| l ∐ mo      | Indonesia  | UA Ukraine   |
| □ nL        | Israel   | UG Uganda  |
| ☐ IS        | Iceland  | ☑ US United States of America  |
| ∑ JP        | Japan  |  |
|             | Kenya  | UZ Uzbekistan  |
|             | Kyrgyzstan   | VN Viet Nam  |
| ⊔ КР        | Democratic People's Republic of Korea  | YU Yugoslavia  |
| [] w        | Danuble of Vano  | ZW Zimbabwe  |
| _           | Republic of Korea  | Check-boxes reserved for designating States (for the purposes of   |
| . =         | Kazakstan Saint Lucia  | a national patent) which have become party to the PCT after issuance of this sheet:  |
|             | Sri Lanka  | <b>D</b>   |
| =           |  |  |
|             | Liberia  | П  |
|             | Lesotho  | kes under Pule 4 9/h) all designations which would be goomitted  |

under the PCT except the designations of the designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

| Box No. VI PRIORITY C  | LAIM  | 1                                  | Further price                              | ority claims are                           | indicated in             | the Supple                   | mental Box  |
|--|---|------------------------------------|--|--|--------------------------|------------------------------|---|
| The priority of the following  |   | ns is hereby cl                    | aimed:                                     |  |                          |                              |   |
| Country<br>(in which, or for which, the<br>application was filed)  |   | g Date<br>onth/year)               |  | Application                                | No.                      | (onl                         | Office of filing<br>by for regional or<br>minional application) |
| item (1)   | 4 June  | 1997                               |  |  |                          |                              |   |
| GB   | 04.06   | .1997                              |  | 9711395.5                                  | •                        |                              |   |
| item (2)   |   |                                    |  |  |                          |                              |   |
|  | •   |                                    |  |  |                          |                              | ,   |
| item (3)   |   | •                                  |  |  |                          |                              |   |
| Mark the following check-box if the international application is the re-   | he certified copy of<br>ceiving Office (a fee | the earlier apple<br>may be requir | ication is to<br>ed):                      | be issued by the                           | Office which j           | for the purpo                | ses of the present  |
| The receiving Office is Bureau a certified copy  | hereby requested<br>of the earlier app        | to prepare an                      | d transmit<br>ntified abo                  | to the Internatio                          | nal<br>(1                | .)                           |   |
| Box No. VII INTERNATI  |   |                                    |  |  |                          |                              |   |
| Cl. in a file terrational Sangahi  | na Authority (IS)                             | A) of two or me                    | sa Internati                               | onal Searchine Au                          | thorities are            |                              |   |
| competent to carry out the internat  | ional search, indica                          | ne the Authority                   | chosen; the                                | two-letter code n                          | ay be used):             |                              |   |
| Earlier Search Fill in where a see<br>out or requested and the Authority<br>Identify such search or request eith<br>Country (or regional Office):  | is now requested to<br>ter by reference to t  | o base the interr                  | ational sear<br>lication (or               | ch, to the extent p<br>the translation the | ossible. on th           | e results of i               | that earlier search.  |
| Country (or regionar ornee).   | _   | aus (ausymusm                      | ,,.  |  |                          |                              |   |
| Box No. VIII CHECK LI  | ST  |                                    |  |  |                          |                              |   |
| This international application the following number of she   | ets:  | 1. Se                              | tional appli<br>parate sign<br>wer of atto | cation is accomed 5.                       |                          | e item(s) n<br>calculation   |   |
| 1. request : 4 2. description : 9  |   | 2. X 20                            | py of gene                                 | ral 6.                                     |                          |                              | tions concerning  |
| 3. claims : 2  | sheets  | pc pc                              | wer of atto                                | mey  | •                        |                              | oorganisms  |
| 4. abstract : 1  |   | 3.                                 | atement exp<br>ck of signa                 | olaining 7.<br>ture                        |                          | leotide and/<br>uence listin | or amino acid<br>g (diskette)                                   |
| 5. drawings : 1  |   | *                                  | iority docu                                |  | Othe                     | er (specify):                |   |
| Figure No of the drawings (if any) should accompany the abstract when it is published.   |   |                                    |  |  |                          |                              |   |
|  |   |                                    |  |  |                          |                              |   |
| Box No. IX SIGNATURE OF APPLICANT OR AGENT  Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from |   |                                    |  |  |                          |                              |   |
| reading the request).  | e mane of the perso                           | 2.8                                | io cupully                                 | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,     |                          | <b>.,</b> , .                | - · · · · · · · · · · · · · · · · · · ·                         |
| For the Applicant<br>Gill Jennings & Eve   | ery   |                                    |  |  |                          |                              |   |
| 1  |   |                                    |  |  |                          |                              |   |
|  |   |                                    |  |  | •                        |                              |   |
| PERRY, Robert Edwar  | PERRY, Robert Edward Date: 3 June 1998        |                                    |  |  |                          |                              | 98  |
| For receiving Office use only  |   |                                    |  |  |                          |                              |   |
| Date of actual receipt of the international application:   | ne purported                                  |                                    |  |  |                          |                              | 2. Drawings:  |
| Corrected date of actual re<br>timely received papers or<br>the purported international  | drawings complet                              | r but<br>ting                      |  |  |                          |                              | received:   |
| Date of timely receipt of the corrections under PCT Art  | he required<br>ticle 11(2):                   |                                    |  |  |                          |                              | not received  |
| International Searching Auspecified by the applicant:  | ithority ISA/                                 |                                    | 6.   | Transmittal of until search fe             | search copy<br>e is paid | delayed                      | · · · · · · · · · · · · · · · · · · ·                           |
|  |   | For Internati                      | ional Burea                                | u use only —                               |                          |                              |   |
| Date of receipt of the record  | сору  |                                    |  |  |                          |                              |   |

#### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference                                 | (Form PCT/ISA/2  | of Transmittal of International Search Report<br>220) as well as, where applicable, item 5 below. |
|---|--|---|
| REP05729W0  | ACTION   |   |
| International application No.   | International filing date (day/month/year)   | (Earliest) Priority Date (day/month/year)   |
| PCT/GB 98/01624   | 03/06/1998   | 04/06/1997  |
| Applicant   |  |   |
| CAMBRIDGE SENSORS LIMITED   | · -4 -4  |   |
| SAMBRIDGE SENSORS LIMITED   | et al.   |   |
| This International Search Report has bee                              | en prepared by this International Searching Aut  | thority and is transmitted to the applicant   |
| according to Article 18. A copy is being tra                          | Ansmitted to the international bureau.   |   |
| This International Search Report consists                             |  |   |
| X It is also accompanied by a cop                                     | by of each prior art document cited in this report   | t.  |
|   |  |   |
| Certain claims were found un  | searchable(see Box I).   |   |
|   |  |   |
| 2. Unity of invention is lacking(s                                    | see Box II).   |   |
| _   |  |   |
| 3. The international application con international search was carried | ntains disclosure of a <b>nucleotide and/or amin</b><br>dout on the basis of the sequence listing  | o acid sequence listing and the   |
|   | d with the international application.  |   |
| . =   | nished by the applicant separately from the inte   | rnational application,  |
| [   | but not accompanied by a statement to the matter going beyond the disclosure in the  | ne effect that it did not include   |
|   | matter going beyond the disclosure in all  | нпternational аррисацон аз шес.   |
| Tra   | nscribed by this Authority   |   |
|   |  |   |
| 4. With regard to the <b>title</b> ,  Y the                           | text is approved as submitted by the applicant   |   |
|   | text has been established by this Authority to re  |   |
|   |  | sau as ionove.  |
|   |  |   |
|   |  |   |
| 5. With regard to the abstract,                                       |  |   |
|   | text is approved as submitted by the applicant   |   |
| Box   | text has been established, according to Rule 3<br>III. The applicant may, within one month from<br>trch Report, submit comments to this Authority. | the date of mailing of this International   |
| •   | ·  |   |
| 6. The figure of the <b>drawings</b> to be publi                      | ished with the abstract is:  |   |
| - · · ·   | suggested by the applicant.  | None of the figures.  |
| X bec   | ause the applicant failed to suggest a figure.   | <del>_</del>  |
| ☐ bec   | ause this figure better characterizes the inventi  | ion   |
|   | adoc ano ngare better endracterizes the invent   | 1011,   |

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 G01N27/403 G01N27/30

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 6 - 601N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

| C. DOCUM | ENTS CONSIDERED TO BE RELEVANT            |
|----------|---|
| Catagoni | Citation of decument with indication when |

| Citation of document, with indication, where appropriate, of the relevant passages                     | Relevant to claim No.  |
|--|--|
| EP 0 215 446 A (FUJI PHOTO FILM CO LTD) 25 March 1987 see page 6, line 8 - page 7, line 3; figures 1,2 | 1,8  |
| EP 0 095 946 A (FUJI PHOTO FILM CO LTD) 7<br>December 1983<br>see page 15, line 19 - line 21           | 1,8  |
| WO 92 14836 A (ASULAB SA) 3 September 1992 see page 6, line 30 - page 7, line 19; figure 4             | 1  |
| EP 0 271 102 A (HORIBA LTD) 15 June 1988 see page 5, line 35 - page 6, line 15/                        | 1  |
|  | EP 0 215 446 A (FUJI PHOTO FILM CO LTD) 25 March 1987 see page 6, line 8 - page 7, line 3; figures 1,2  EP 0 095 946 A (FUJI PHOTO FILM CO LTD) 7 December 1983 see page 15, line 19 - line 21  WO 92 14836 A (ASULAB SA) 3 September 1992 see page 6, line 30 - page 7, line 19; figure 4  EP 0 271 102 A (HORIBA LTD) 15 June 1988 see page 5, line 35 - page 6, line 15 |

| X Further documents are listed in the continuation of box C.  | Patent family members are listed in annex.  |
|---|---|
| <ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filing date</li> <li>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul> | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "&" document member of the same patent family |
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